K012526

SEP 1 4 2001

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: BIOTEQUE CORPORATION
   Address: Suite 402, 4th Fl, No. 136, Sec.3,Jen-Ai Road, Taipei, R.O.C.
   Phone: 886-2-2708-6716
   Fax: 886-2-2707-6610
   Contact: Mr. William Lee (General Manager)

2. Device Name
   Trade Name: **BIOTEQ® SCALP VEIN SET**
   Common Name: **SCALP VEIN SET**
   Classification name: **SET, ADMINISTRATION, INTRAVASCULAR**

3. Classification: Class II

4. Predicate Device: **TERUMO SURFLO WINGED INFUSION SET (K771204)**
   EXEL BUTTERFLY SCALP VEIN SET (K862491)

5. Device Description: **BIOTEQ® SCALP VEIN SET (BS-120 (22G); BS-121(23G) ; BS-122(24G))**consist of the following 5 major components: Protective cap for needle, the stainless needle, the plastic butterfly wing , the PVC Tube, the PVC safety Cap. These 5 major components assembled together as **SCALP VEIN SET** for use as a pathway to administer medical fluid from extracorporeal system through the device into venous blood.

6. Intended Use: **BIOTEQ® SCALP VEIN SET** act as a pathway to administer parenteral fluid/ medication into the patient's vascular system.

7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 10993 series, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions:

The **BIOTEQ® SCALP VEIN SET** have the same intended use and similar technological characteristics as the **TERUMO SURFLO WINGED INFUSION SET (K771204) & EXEL BUTTERFLY SCALP VEIN SET (K862491)**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **BIOTEQ® SCALP VEIN SET** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

C/O Mr. Allen Reich
Consultant
BioTeque Corporation
900 N. Switzer Canyon Drive #142
Flaggstaff, Arizona 86001

Re: K012526
Trade/Device Name: BioTeque Scalp Vein Set
Regulation Number: 880.5440
Regulation Name: Scalp Vein Set
Regulatory Class: II
Product Code: FPA
Dated: July 31, 2001
Received: August 6, 2001

Dear Mr. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K 012526

DEVICE NAME: **BIOTEQ® SCALP VEIN SET**

BIOTEQUE CORPORATION

INDICATIONS FOR USE:

BIOTEQ® SCALP VEIN SET act as a pathway to administer parenteral fluid/ medication into the patient's vascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012526